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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,048	07/28/2003	Stuart Brown	26859-002UTIL	7394
30623 7590 01/17/2007 MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111				
EXAMINER ROGERS, KRISTIN D				
ART UNIT 3736 PAPER NUMBER				
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/17/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/629,048

Applicant(s)

BROWN, STUART

Examiner

Kristin D. Rogers

Art Unit

3736

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11, 13-15, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12, 16-23, and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed October 19, 2006 have been fully considered but they are not persuasive.

2. In regard to the Applicant's argument that Chin et al. fails to suggest an instrument having a plurality of tissue sampling devices positioned in an array extending along the longitudinal axis. The Examiner disagrees. Chin et al. shows a housing defining a longitudinal axis, from the distal to the proximal end, having a plurality of tissue sampling devices extending along the longitudinal axis. The Examiner submits Figure 1 of Chine et al. as evidence of the claimed subject matter. Therefore, the Examiner believes that Chin et al. fairly teaches the invention claimed by Applicant.

3. In regard to Applicant's argument that Levin does not teach or suggest inserting an instrument having an array of tissue sampling devices positioned along its length into a subject. The Examiner disagrees. Levin shows an instrument for removing a tissue sample comprising an array of tissue sampling devices for inserting into a patient. The Examiner submits Figure 2 illustrating the plurality of sampling devices 12 and 14 having cutting edges 42 and 44 for sampling tissue. Therefore, the Examiner believes that Levin fairly teaches the invention claimed by Applicant.

4. In regard to Applicant's arguments that none of Chin, Levin and Burbank teaches or discloses inserting into the subject an instrument comprising a plurality of controllable tissue sampling devices arranged in an array along a longitudinal axis of a housing. The Examiner disagrees. The Examiner submits that Chin and Levin teach the

invention claimed by Applicant as discussed above. Burbank et al. teaches a tissue collection device including a method of a deploying control element 104 that emits RF-transmitted signals 106 for communication. Therefore, the Examiner believes that Chin, Levin, and Burbank fairly teach the invention claimed by Applicant.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chin et al. (5414182). In regard to claim 1, Chin et al. shows an instrument for removing a tissue sample including a housing 101 defining a longitudinal axis comprising a plurality of tissue sampling devices comprising an isolated chamber 104 and 105 controllable to receive tissue. In regard to claim 2, the housing comprises an interior lumen (inside housing cover 102) with deployment control element 131. In regard to claim 3, the isolated chamber of the sampling device does not communicate said tissue sample to said interior lumen shown in figure 2 and 3A. In regard to claim 4, the housing 101 is solid and the deployment device 131 is located on the exterior surface of the housing 101 (Figure 1). In regard to claims 8-10, the sampling devices 104 and 105 are radially disposed, along the length of the outside diameter of the instrument (column 3 lines 55-57 Figure 1).

7. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Levin (5295990). Levin shows a method of extracting tissue samples including inserting a housing with a plurality of mechanical tissue sampling/extraction devices 12 and 14 comprising an isolated chamber 36, heating the sampling devices with heating element, electrosurgical generator, causing the mechanical tissue sampling devices to collect and retain a tissue sample into chamber 36 and then removing the instrument from the subject (column 4, lines 12-26 and column 2, lines 35-41). In regard to claim 21, an electrical current is passed through a portion of the extraction devices 12 and 14 (column 4 lines 27-32).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 5-6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Burbank et al. (20020193705). Chin et al. shows an instrument for removing tissue but lacks a deployment control element that emits a signal and vacuum sampling chambers. In regard to claims 5 and 6, Burbank et al. teaches a tissue collection device including a deployment control element 104 that emits RF-transmitted signals 106. In regard to claim 12, Burbank et al. teaches a tissue sampling device including a vacuum sampling chamber 114 and 108 (Figure 1) for the purpose of collecting tissue. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Chin et al. with sampling chambers that comprised a vacuum and a deployment device for emitting RF-transmitted signals as taught by Burbank et al. since such modification would provide the sample device with communication means and vacuum tissue sampling.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Levin (5295990). Chin et al. shows an instrument for removing tissue, but lacks a deployment device with a heating element and a chamber having a heat conducting cover. Levin teaches an instrument for removing tissue including a deployment device 10 comprises a heating element, electrosurgical generator, wherein the chamber 36 comprises heat conducting cover (column 4 lines 12-26). It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Chin et al. with a deployment device having a heating element and a chamber with a heat conductive cover for the purpose of providing heating means to the tissue sampling device.

12. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Megahed (4305406). Chin et al. shows a tissue collection device including a housing 101 comprising a plurality of tissue sampling devices comprising an isolated chamber 104 and 105 controllable to receive tissue, but lacks disclosure of the volume of the chamber. Megahed teaches a device for collection liquid (blood) that comprises an isolated collection chamber 50 having a volume of 400 to 500 cubic millimeters (column 5 lines 25-31). Megahed does not disclose expressly a chamber volume ranging from 0.001 to 1 cubic millimeters. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to construct the chamber to have a volume of 0.001 to 1 cubic millimeter because Applicant has not disclosed that having a chamber volume of 0.001 to 1 cubic millimeter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the chamber volume as taught by Megahed or the claimed volume of 0.001 to 1 cubic millimeter because both chamber volumes perform the same function of collecting and isolating a sample. Therefore, it would have been an obvious matter of design choice to modify Chin et al. to obtain the invention as specified by Applicant in claim 16.

13. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin et al. in view of Burbank et al. and in further view of Levin. In regard to claim 17, Chin et al. shows a method of inserting a tissue sampling device including a housing 101 comprising a plurality of tissue sampling devices comprising an isolated chamber

104 and 105 controllable to receive tissue and a deployment device 131, but lacks a method of contacting the deployment device with a deployment signal and removing the tissue sample and sealing the chamber. Burbank et al. teaches a tissue collection device including a method of a deploying control element 104 that emits RF-transmitted signals 106 for communication. Levin teaches an instrument for removing tissue including a method of deploying deployment device 10 comprising a heating element, electrosurgical generator, wherein the chamber 36 comprises heat conductive cover which seals chamber 36. In regard to claim 18, Chin et al. teaches a method of deploying sampling devices 104 and 105 simultaneously (column 4, lines 32-35). In regard to claim 19, Levin teaches a method in which the sampling device is deployed temporally (column 3, lines 66-68). Therefore it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Chin et al. with a method for contacting the deployment signal and removing a tissue sample and sealing the chamber as taught by Burbank et al. and Levin for the purpose of providing communication, heating and sealing means for the tissue collection instrument.

14. Claims 22-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Levin and Burbank et al. Levin shows a method of extracting multiple tissue samples, but lacks a method of applying a differential pressure or pressurizing the chamber. In regard to claims 22 and 23, Burbank et al. teaches a method of applying a vacuum 108 to the sample chamber 114 in which tissue extractor 102 extracts tissue sample into sampling chamber 114 but sucking. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Levin with a method

of applying a differential pressure or pressurizing the chamber as taught by Burbank et al. since such modification would provide a method of applying a differential pressure to extract the tissue sample.

15. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levin in view of Larose (5531756). Levin shows a method of extracting tissue but lacks a method of imaging a location of the sample. Larose teaches a method of extracting tissue that comprises of a method of inserting a fiber-optic device 62 into the location of the tissue sample for imaging the site on a monitor 66. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify Levin with a fiber-optic device as taught by Larose for the purpose of providing a method of imaging a location of the sample fiber optically.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDR

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Max Hindenburg
Max Hindenburg
Supervisor